

Application No. 10/072,259
Amendment "C" dated July 21, 2005
Reply to Office Action mailed June 14, 2005

REMARKS

Claims 1, 2 and 7-23 remain pending in the application, wherein claims 15 and 21-23 have been amended. Reconsideration and withdrawal of the claim rejections are respectfully requested based on the following remarks.

The Office Action rejects claims 1, 2, 7-12 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Ko (JP '733) in view of Takai et al. (US 6,432,188)¹ and Breads et al. (US 5,035,613). The Office Action further rejects claims 13 and 15-23 under various combinations of references, all of which are based on Ko as the sole primary reference.

In response, Applicants note that Ko is substantially similar, if not identical, to Hiro et al. (US 5,666,974). Hiro was previously cited in the office action dated July 1, 2004 ("First Office Action"). Applicants successfully amended and argued around Hiro in Amendment A and Response, filed September 9, 2004. The second office action dated December 15, 2004 ("Second Office Action") acknowledged that the then-pending claims were patentable over Hiro. For this reason, the Second Office Action presented new grounds for rejection, and made the rejection final on the grounds that the amendments that successfully distinguished over Hiro necessitated the new grounds for rejection. Second Office Action, p. 6. Because every claim rejection set forth in the present Office Action is based on a reference that was already cited and then removed based on a previous amendment, Applicants submit that the claims as now presented are patentable over the applied art.

Hiro appears to be the U.S. counterpart to Ko. This is evidenced by the fact that both patents are assigned to Okamoto Industries, Inc. of Tokyo, Japan, share the same title (Mouthpiece Prototype), and share a common inventor (Akinori Watanabe). The U.S. application was filed April 30, 1996, exactly 18 months after the filing date of the Japanese application (Nov. 1, 1994), in order to beat the publication date of the corresponding Japanese application. Figures 1 and 2 of Ko are identical to Figures 1 and 2 of Hiro in every way, including the same shape and shading and the identical use of numbers to identify the

¹ Applicants note that Takai has an issue date (Aug. 13, 2002) that is subsequent to the filing date (Feb. 6, 2002). However, because Takai is a national phase application filed under 35 U.S.C. § 371 before the implementation date of the AIPA (November 29, 2000), its effective filing date for purposes of applying 35 U.S.C. § 102(e) is April 12, 2000 rather than the international filing date (Nov. 16, 1998). Applicants do not admit that Takai is in fact prior art and reserve the right to establish an invention date that precedes April 12, 2000 in order to remove Takai as a reference.

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components. Moreover, the translation of the Abstract provided by the Examiner further demonstrates the similarities between Ko and Hiro.

As discussed in Amendment A and Response filed September 9, 2004, Hiro (and now Ko) discloses a specially designed "prototype" mouth piece having an H-shaped cross section in order for a single device to cover both the user's upper and lower teeth at the same time using a single device. Col. 1, line 66 – col. 2, line 5; Figures 1 and 2. Claim 1 was previously amended to substantially incorporate the limitations of cancelled dependent claims 3-5 in order to recite the use of "a protective mouth guard that is substantially U-shaped or L-shaped so as to fit over and cover at least a portion of a person's upper or lower teeth". Claim 18 was similarly amended at that time. A protective mouth guard that is "substantially U-shaped or L-shaped" is incapable of covering both a person's upper teeth and lower teeth at the same time. Because Hiro discloses a specially designed mouth guard having an H-shaped cross section that covers both the upper and lower teeth at the same time, Hiro et al. fails to teach or suggest a device that is either U-shaped or L-shaped.

Ko (JP '733") is similarly deficient. According to the English Abstract provided by the PTO, Ko teaches that the "**PURPOSE**" of the invention is "[t]o obtain a mouthpiece having a shape adapted to the shape of the dentition of the maxillary teeth and the mandibular teeth" (emphasis added). This "purpose" is accomplished "by forming the cross-sectional shape consisting of an occlusion part fittable in a loose fitting state onto the dentition of the maxillary teeth and the mandibular teeth, an outer wall part and a lower wall part into an H shape" (emphasis added). The remaining portion of the Abstract also describes the "H shape" of the mouthpiece and the ability of this design feature to cover the dentition of both the maxillary teeth and the mandibular teeth at the same time when forming the final mouthpiece, which is a single, unitary device. In view of the clear teachings of Ko, the H shape of the disclosed mouthpiece is important for it to carry out its intended "purpose" of covering both the maxillary teeth and mandibular teeth at the same time using a single device.

As discussed in Amendment "A" and Response, Hiro (the apparent U.S. counterpart to Ko) discloses the importance to the invention of providing an H-shaped mouth piece that is configured to cover both the person's upper and lower teeth at the same time. In addition, Hiro disparages the use of a "conventional mouth piece" that "forms a shape similar to 'U' figure" that is "produced to fit to the shape of maxilla teeth". Col. 1, lines 53-56. According to Hiro, U-

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shaped mouth pieces configured to cover only the maxilla teeth do not provide "an effective improvement on dynamic muscles powered during a match or game". Col. 1, lines 61-63. The solution to this alleged problem is the use of a "mouth piece forming a cross sectional shape of 'H' figure which fits both maxilla teeth and mandibular teeth" at the same time. Col. 1, line 66 – col. 2, line 3 (emphasis added). Such a tray "gives a good result not only in static muscles power but also in dynamic muscles power". Col. 2, lines 3-5. Accordingly, Hiro teaches away from the use of dental trays that cover only the upper or lower teeth, but not both at the same time using a single device. As a result, one of skill in the art would not have been motivated to modify Hiro to eliminate the "H" shape because to do so would prevent it from performing its intended purpose (*i.e.*, of covering both the upper and lower teeth at the same time using a single device). The same analysis is equally applicable to Ko.

According to MPEP 2143.02, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification". MPEP 2143.02 (under the heading "THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE") (citing *In Re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir.)).

As discussed above, the stated "purpose" of Ko is as follows: "To obtain a mouthpiece having a shape adapted to the shape of the dentition of the maxillary teeth and the mandibular teeth by forming the cross-sectional shape consisting of an occlusion part fittable in a loose fitting state onto the dentition of the maxillary teeth and the mandibular teeth, an outer wall part and a lower wall part into an H shape" (emphasis added). Ko JP '733, Abstract. Based on the clear mandate of MPEP 2143.02, one of skill in the art, as a matter of law, would not have been motivated to modify Ko to provide a dental tray that covers only the upper or lower teeth, but not both at the same time using a single device, because to do so would render the Ko device unsatisfactory for its stated "purpose" of covering both the upper and lower teeth. On this basis alone, claims 1 and 18 as presented, as well as any claims that depend therefrom, are patentable over the combination of Ko and any other art of record.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of all claim rejections relating to claims 1, 2, 7-14 and 18-20.

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Applicants have now amended independent claim 22 to recite "a protective outer mouth guard that is substantially U-shaped or L-shaped". Claim 23 was amended to claim a kit that comprises "at least one protective outer mouth guard or mouth guard precursor that is substantially U-shaped or L-shaped". As discussed above, it would be contrary to the teachings of Ko to modify the H shaped prototype mouthpiece to yield a device "that is substantially U-shaped or L-shaped". To do so would render the Ko device unsatisfactory for its stated "purpose". Accordingly, Applicants submit that claims 22 and 23 are also patentable over the art of record for at least this reason.

Independent claim 15 alternative claims a method that includes the act of "providing a custom-fitted protective outer mouth guard previously customized using a person's teeth or model of the person's teeth so as to cover and fit at least a portion of a person's teeth in a customized manner" (underlining shows language added by amendment). The curable material is then inserted into the "custom-fitted protective outer mouth guard". Support for customizing an outer protective mouth guard using a person's teeth or a model of the person's teeth is set forth in the application at page 7, paragraphs [024] and [025].

To date, the PTO has never cited to a single reference, or any combination of references, that teaches or suggests introducing a deformable and curable elastomeric material into a custom-fitted protective outer mouth guard that was "previously customized using a person's teeth or model of the person's teeth so as to cover and fit at least a portion of the person's teeth in a customized manner". Ko JP '733 teaches no such thing, as evidenced by the extreme uniformity of the H shaped cross section of the mouthpiece shown in Figures 1 and 2 into which a silicone rubber is placed. Neither do Takai nor Wagner (US 5,566,684), the only other references cited against claim 15.

Takai generally relates to an impression material composition, which may be used for a wide variety of different uses, including for "modeling rows of teeth", "manufacture of mouthpieces", "modeling the external ear", "modeling a foot", "modeling the digits of a hand, foot, etc.", "manufacture of silicon rubber replicates, etc.", "compensating for the loss of such body parts", "manufacture of replicas of humans, animals, and other natural objects and articles, etc.", "model-making and other hobbies", "molding of automobile parts, etc.". Col. 1, ll. 11-23. Aside from the general mention of "manufacture of mouthpieces", in addition to the many other uses of the disclosed composition, nothing more is said concerning how mouthpieces are actually

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manufactured. Takai neither teaches nor suggests placing the disclosed compositions into a protective outer mouth guard to form a "protective cushioning mouth guard having an inner cushioning layer" that is positioned within the "protective outer mouth guard," much less an outer mouth guard that was "previously customized using a person's teeth or model of the person's teeth so as to cover and fit at least a portion of the person's teeth in a customized manner".

Wagner discloses a "do-it-yourself custom fit mouthguard" that "includes a thermoplastic channel trough in the configuration of a maxillary arch. Molded to the trough is a low melt temperature deformable thermoplastic upper fill." Col. 1, ll. 62-65 (emphasis added). Thus, the entire Wagner tray is "thermoplastic". Wagner neither teaches nor suggests "introducing a quantity of a deformable and curable elastomeric material into [a] protective outer mouth guard that is able to form a dental impression therein without heating to above a melting point", much less a "custom-fitted protective outer mouth guard" that was "previously customized using a person's teeth or model of the person's teeth so as to cover and fit at least a portion of the person's teeth in a customized manner".

In short, none of Ko, Takai or Wagner, of any combination thereof, teach or suggest every limitation of claim 15 as now amended, or any claim depending therefrom. Accordingly, Applicants respectfully request reconsideration and withdrawal of the all rejections relating to claims 15-17.

Claim 21 alternatively claims a method of manufacturing a protective cushioning mouth guard that includes the act of "applying an adhesive material to the protective outer mouth guard" in order to "yield a protective cushioning mouth guard having an inner cushioning layer formed from the curable elastomeric material positioned within the protective outer mouth guard", with "the adhesive material increasing bond strength between the inner cushioning layer formed from the curable elastomeric material and the protective outer mouth guard compared to a bond strength between the inner cushioning layer and protective outer mouth guard in the absence of the adhesive material." The use of an adhesive decreases the likelihood that the inner cushioning layer will separate from the outer protective layer during use. None of the cited references teach or suggest the use of an adhesive to enhance the bond between a curable (or cured) elastomeric material and a protective outer mouth guard.

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The sole primary reference Ko fails to provide any motivation to use an adhesive. According to its presumptive U.S. counterpart (Hiro), "silicone rubber is desirable to be used because the adhesive strength between the prototype is strong". Col. 3, ll. 2-4 (emphasis added). Thus, the silicone rubber material used in Ko has "strong" "adhesive strength", as evidenced by the teaching in Hiro. Because of this, one of skill in the art would not have been motivated to alter Ko in order to use an adhesive, since the "adhesive strength" is already said to be "strong". The only other references cited against claim 21, Takai and Grossberg (US 3,214,129), also fail to teach or suggest "applying an adhesive material to the protective outer mouth guard" in order to increase bond strength between an inner cushioning layer formed from a curable elastomeric material and a protective outer mouth guard.

Takai neither teaches nor suggests placing the disclosed impression material composition into a protective outer mouth guard, much less in combination with an adhesive.

Grossberg, on the other hand, neither teaches nor suggests placing a curable elastomeric material of any kind into a protective outer mouth guard, much less in combination with an adhesive material to increase the bond strength between these specific materials. Instead, Grossberg discloses a "teeth protector" that includes a "channel 11" into which is "mounted therein a body of an impression-taking material 16". Col. 2, ll. 9-10. "Impression-taking material 16 . . . may comprise numerous plastic or resinous compositions which are well-known in the art to have the thermo-plastic properties desired for purposes of taking and retaining an accurate dental impression." Col. 2, ll. 14-18 (emphasis added). "Impression-taking material 16 . . . will soften sufficiently to be molded about the teeth at a temperature in the range from about 120° F. to about 160° F. and which, upon cooling below this range of temperature and particularly to normal atmospheric or internal mouth temperatures, will permanently remain an accurate impression of the teeth." Col. 2, ll. 43-50 (emphasis added).

It is clear to one of skill in the art that the impression taking material 16 loaded within channel 11 of the Grossberg device is a "thermoplastic" material that only becomes deformable at elevated temperatures (*i.e.*, between about 120-160° F) and that solidifies upon cooling to below this temperature. At room temperature, such thermoplastic materials are solid. Because the "impression-taking material 16" is solid at room temperature, it is advantageously "securely fastened" to the channel 11 using an "adhesive" or "by mechanical connector means of a conventional type". Col. 2, ll. 11-13. In other words, two solid thermoplastic materials typically

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do not adhere to each other at room temperature. For that reason, an adhesive or mechanical attachment means are necessary to fasten the two initially solid materials together.

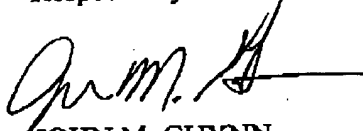
That is not in the case when using the silicone rubber material of Ko. As discussed above, "silicone rubber is desirable to be used because the adhesive strength between the prototype is strong". Hiro, col. 3, ll. 2-4 (emphasis added). In view of this, Applicants submit that the prior art fails to provide any motivation for modifying Ko in order to use an adhesive between the silicone rubber and the prototype mouthguard.

Moreover, just because an adhesive is able bond two initially solid thermoplastic materials together as in Grossberg does not mean that the same adhesive would necessarily increase the adhesive bond between the silicone rubber material and the disclosed prototype mouthguard of Ko. Because Grossberg fails to teach or suggest an adhesive known to increase bond strength between a curable elastomeric material such as silicone rubber and a protective outer mouthguard, it would require undue testing to identify the adhesive (or adhesives) from among the thousands of known adhesives that would necessarily have the effect of "increasing bond strength between the inner cushioning layer formed from the curable elastomeric material and the protective outer mouth guard compared to a bond strength between the inner cushioning layer and protective outer mouth guard in the absence of the adhesive material". For this additional reason, Applicants submit that claim 21 is patentable over the art of record.

In conclusion, Applicants submit that the claims as now amended are in allowable form. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application, which may be clarified through a telephone interview or that can be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 21st day of July 2005.

Respectfully submitted,



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